REMARKS

Claims 1, 3, 4, 6-13, 17, 19, 20, 22-25, and 38 were previously pending, of which claims 7-9 have been withdrawn from consideration. Claims 1, 3, 4, 11, 12, 17, 19, 20, 22-25, and 38 are currently amended, claim 10 is canceled without prejudice, and no new claims are added by this Amendment. No new matter has been introduced. Upon entry of this Amendment, claims 1, 3, 4, 6-9, 11-13, 17, 19, 20, 22-25, and 38 remain pending, of which claims 7-9 have been withdrawn from consideration.

Each of independent claims 1 and 17 is currently amended, in part, to specify the claimed method includes a selection step whereby an anti-PSGL-1 antibody that specifically binds to P-Selectin Glycoprotein Ligand-1 (PSGL-1) on the surface of an activated T cell is selected based on ability of the anti-PSGL-1 antibody to induce apoptosis of the activated T cell. Support for such selection step can be found, for example, in the passage entitled "Screening Assays for Compounds that Modulate PSGL-1 Function" spanning pages 12-15 of the specification, particularly page 15, lines 7-9.

Each of independent claims 1 and 17, as well as claim 25 which depends from claim 17, is currently amended, at least in part, to omit the phrase "or antigen-binding fragment thereof".

Claim 4 is currently amended, for greater clarity, to specify the administering is administering to the individual. Applicant submits such amendment does not alter the scope of the claim in any way.

Each of claims 11 and 12 is currently amended to specify the T cell is an activated T cell, in accordance with current amendment to claim 1 from which these claims depend.

Similarly, each of claims 20, 22-25, and 38 is amended to specify the T cell is an activated T cell, in accordance with current amendment to claim 17 from which these claims depend.

Priority

In item number 3 beginning on page 3 of the Office Action, the Examiner maintained his prior position that the provisional application to which the instant application claims priority does not appear to provide sufficient written description for the claimed limitations. Applicant, having previously addressed this issue on more than one occasion, respectfully disagrees but acknowledges the Examiner has maintained his position.

Rejection Under 35 U.S.C. § 112, First Paragraph (Written Description)

In item number 5 beginning on page 5 of the Office Action, the Examiner rejected claims 4 and 20 under 35 U.S.C. § 112, first paragraph, for alleged lack of written description. More particularly, the Examiner asserted that the specification as originally filed does not provide support for the claimed "antibody that binds to the monoclonal antibody and induces the cross-linking of a plurality of PSGL-1 antigen on the surface of the T cell." Page 6 of Office Action. The Examiner then acknowledged disclosure in Examples 3 and 10 of two species of cross-linking antibodies (anti-hamster Ig and anti-mouse Ig).

It appears that the Examiner has essentially taken the position that written description of "antibody that binds to the monoclonal antibody and induces the cross-linking of a plurality of PSGL-1 antigen on the surface of the T cell" requires *in haec verba* support in the specification as filed. Applicant respectfully disagrees with this position and, for reasons stated below, respectfully requests reconsideration.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Vas-Cath v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991). It is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification. MPEP 2163. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set

forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997). Possession may be shown in a variety of ways, including description of an actual reduction to practice, or by showing that the invention was "ready for patenting", such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show the applicant was in possession of the claimed invention. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68 (1998); Regents of the University of California v. Eli Lilly, 119 F.3d 1559, 1568 (Fed. Cir. 1997). Finally, while there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure. MPEP 2163.

In the instant application, claims 4, 20, and 31 as originally filed specify "administering an agent that binds to the monoclonal antibody and induces the cross-linking of a plurality of PSGL-1 antigens on the surface of the T cell" (claim 4) and "contacting the monoclonal antibody with an agent that binds to the monoclonal antibody and induces the cross-linking of a plurality of PSGL-1 antigens on the surface of the (T cell or NK) cell" (claims 20 and 31), respectively. Claims 4 and 20 were subsequently amended to substitute "antibody" for "agent"; claim 31 was subsequently withdrawn and later canceled as it was directed to a non-elected invention.

Applicant respectfully submits that the amended claim language of pending claims 4 and 20 is adequately supported by the words of Examples 3 and 10, as well as by Figures 1 and 8, all evidencing actual reduction to practice in respect of the claimed methods involving cross-linking antibodies that bind to the monoclonal antibody and induce cross-linking of a plurality of PSGL-1 antigens on the surface of the T cell (or NK cell). Accordingly, Applicant submits that the patent specification does indeed describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. Vas-Cath v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991). Applicant further submits that it shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words [and] figures ... that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 (Fed.

Cir. 1997). Further, Applicant submits it has demonstrated possession by description of an actual reduction to practice. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68 (1998); Regents of the University of California v. Eli Lilly, 119 F.3d 1559, 1568 (Fed. Cir. 1997). Any lack of *in haec verba* description does not necessarily result in inadequate written description because the specification provides express, implicit, and/or inherent disclosure of what is claimed. MPEP 2163.

Accordingly, Applicant respectfully submits claims 4 and 20 have adequate written description support and therefore requests the Examiner to reconsider and withdraw the rejection of claims 4 and 20 under 35 U.S.C. §112, first paragraph, for alleged lack of written description.

Rejection Under 35 U.S.C. § 112, First Paragraph (Enablement)

Applicant acknowledges that in item number 6 beginning on page 7 of the Office Action, the Examiner indicated that the previous scope of enablement rejection has been withdrawn.

In item number 7 beginning on page 7 of the Office Action, the Examiner rejected, on New Grounds of Rejection, claims 1, 3, 4, 6, 10-13, 17, 19, 20, 22-25, and 38 under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement. More particularly, the New Grounds of Rejection appear to relate to the limitation "antigen-binding fragments" as applied by the Examiner to all of the claims. Page 8 of Office Action. Furthermore, at the bottom of page 8 of the Office Action the Examiner asserted that the invention encompasses any "antibody fragment that binds to the monoclonal antibody and induces the cross-linking of a plurality of PSGL-1 antigens on the surface of cell" [emphasis supplied by Examiner], citing the Summary of the Invention, particularly page 5, paragraph 3 of the specification. For reasons stated below, Applicant respectfully requests reconsideration.

Applicant respectfully traverses the Examiner's position that all claims "read on" antigen-binding fragments as applied to any antibody in any claim. Applicant submits the Examiner has taken liberty to read features into the claims that result in the New Grounds of Rejection. For example, the supposed quotation "antibody fragment that binds to the

monoclonal antibody and induces the cross-linking of a plurality of PSGL-1 antigens on the surface of cell" [emphasis supplied by Examiner] cannot be found in the Summary of the Invention, particularly page 5, paragraph 3 of the specification, as suggested by the Examiner.

Without necessarily conceding the validity of the Examiner's position, Applicant has currently amended claims 1, 17, and 25 to omit the phrase "or antigen-binding fragment thereof". None of the claims as currently amended recite the offending feature "antigen-binding fragments". Accordingly, Applicant respectfully submits the New Grounds of Rejection are rendered moot and therefore requests the Examiner to reconsider and withdraw the rejection of claims 1, 3, 4, 6, 10-13, 17, 19, 20, 22-25, and 38 under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement.

Applicant expressly reserves the right to pursue claims directed in pertinent part to antigen-binding fragments of the anti-PSGL-1 antibodies of the invention in one or more continuing applications.

Rejection Under 35 U.S.C. § 102(b)

In item number 11 beginning on page 12 of the Office Action, the Examiner rejected claims 1, 3, 6, 10-12, 17, 19, 22-24, and 38 under 35 U.S.C. § 102(b) for alleged anticipation by Larsen et al. (U.S. Patent No. 5,840,679; "Larsen") essentially for reasons of record and in further evidence of Chen et al. (*Blood* 104:3233-3242 (2004); "Chen"). Near the bottom of page 13 of the Office Action the Examiner asserted that "much of applicant's arguments in conjunction with the Lin Declaration appear to rely on an asserted new mechanism of action of anti-PSGL-1 antibodies rather than focusing on new anti-PSGL-1 antibody epitopes or other characteristics." The Examiner acknowledged, however, that Applicant in conjunction with the Lin Declaration note that certain anti-PSGL-1 antibodies, but not all anti-PSGL-1 antibodies, are capable of inducing apoptosis [of] mature, activated T cells and that certain apoptosis-inducing anti-PSGL-1 antibodies do not interfere with PSGL-1-mediated interactions with ... selectins. The Examiner reiterated on page 14 of the Office Action that the mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or

obvious. More particularly, the Examiner appears to have taken the position that Larsen, though silent concerning apoptosis induction by anti-PSGL-1 antibody disclosed in Larsen, nonetheless anticipates the instant claimed invention. Further, the Examiner stated on page 15 of the Office Action that "While the invention may be based on the discovery that T cells can be depleted and/or induced to undergo apoptosis by the engagement of the T cell surface antigen PSGL[-1] ..., there is insufficient objective evidence that the treatment of anti-PSGL-1 antibodies in the prior art do not result in the claimed cell death of T cells via cross-linking ... and/or the presence of PSGL-1 expressing mature activated T cells during the administration of PSGL-1-specific antibodies." [Emphasis in original.] Finally, the Examiner asserted, e.g., on page 16 of the Office Action, that "it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure." For reasons stated below, Applicant respectfully requests reconsideration.

Each of independent claims 1 and 17 is currently amended, in part, to specify the claimed method includes a selection step whereby an anti-PSGL-1 antibody that specifically binds to PSGL-1 on the surface of an activated T cell is selected based on ability of the anti-PSGL-1 antibody to induce apoptosis of the activated T cell. This added selection step clearly distinguishes the claimed invention over Larsen. More particularly, this added selection step clearly results in a manipulative difference in the method steps when compared to Larsen. As acknowledged by the Examiner, Larsen makes no teaching concerning the ability of any anti-PSGL-1 antibody to induce apoptosis of T cells or NK cells (see, for example, the first paragraph on page 16 of the Office Action). Consistent with this lack of teaching by Larsen, Larsen does not teach a selection step as currently claimed. Accordingly, Larsen does not anticipate the claims as currently amended. Applicant points out to the Examiner that the claims as amended specify that the selected anti-PSGL-1 antibody is capable of inducing apoptosis of activated T cells. Such amendment to specify activated T cells is supported by the specification as filed and comports with the teachings of Chen.

Claim 10 is canceled by this Amendment, rendering moot its rejection under 35 U.S.C. § 102(b).

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of claims 1, 3, 6, 10-12, 17, 19, 22-24, and 38 under 35 U.S.C. § 102(b) for alleged anticipation by Larsen and in further evidence of Chen.

Rejection Under 35 U.S.C. § 102(e)

In item number 12 beginning on page 17 of the Office Action, the Examiner newly rejected claims 1, 3, 4, 6, 10-13, 17, 19, 20, 22-25, and 38 under 35 U.S.C. § 102(e) for alleged anticipation by Lazarovits et al. (U.S. Patent Application Publication No. 2004/0002450 A1; "Lazarovits") as further evidenced by the Lin 132 Declaration, filed 02/01/2007. According to the Examiner, Lazarovits teaches "methods of treating inflammation, including autoimmune diseases with PSGL-1-specific antibodies ..., including the Y1, Y17, and KPL1 epitopic specificities." The Examiner also pointed out that the Lin 132 Declaration "acknowledges that KPL1-specific PSGL-1-specific antibodies can induce apoptosis." Page17 of Office Action. For reasons stated below, Applicant respectfully requests reconsideration.

As noted above, each of independent claims 1 and 17 is currently amended, in part, to specify the claimed method includes a selection step whereby an anti-PSGL-1 antibody that specifically binds to PSGL-1 on the surface of an activated T cell is selected based on ability of the anti-PSGL-1 antibody to induce apoptosis of the activated T cell.

Lazarovits teaches certain antibodies and variants of such antibodies that are capable of binding to epitopes characterized by one or more sulfated tyrosine residues. Significantly, Lazarovits, similar to Larsen (above), makes no teaching concerning the ability of any anti-PSGL-1 antibody (including KPL1) to induce apoptosis of T cells or NK cells. Consistent with this lack of teaching by Lazarovits, Lazarovits also does not teach a selection step as currently claimed. Accordingly, Lazarovits does not anticipate the claims as currently amended. The selection step missing from Lazarovits cannot properly be supplied by the Lin 132 Declaration.

Claim 10 is canceled by this Amendment, rendering moot its rejection under 35 U.S.C. § 102(e).

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of claims 1, 3, 4, 6, 10-13, 17, 19, 20, 22-25, and 38 under 35 U.S.C. § 102(e) for alleged anticipation by Lazarovits as further evidenced by the Lin 132 Declaration.

Rejection Under 35 U.S.C. § 103

In item number 13 beginning on page 18 of the Office Action, the Examiner rejected claims 1, 3, 4, 6, 10-13, 17, 19, 20, 22-25, and 38 under 35 U.S.C. § 103(a) as obvious over Larsen (*supra*) in view of Trembleau et al. (*J. Immunol.* 163:2960-2968 (1999); "Trembleau"), Yago et al. (*J. Immunol.* 161:1140-1145 (1998); "Yago"), Hirata et al. (*J. Exp. Med.* 192:1669-1675 (2000); "Hirata"), and Cobbold et al. (U.S. Patent No. 6,056,956; "Cobbold") and as further evidenced by Chen (*supra*) essentially for the reasons of record. More particularly, the Examiner asserted on page 18 of the Office Action that "While the invention may be based on the discovery that T cells can be depleted and/or induced to undergo apoptosis by the engagement of the T cell surface antigen PSGL[-1] ..., there is insufficient objective evidence that the treatment of anti-PSGL-1 antibodies in the prior art do not result in the claimed cell death of T cells via cross-linking ... and/or the presence of PSGL-1 expressing mature activated T cells during the administration of PSGL-1-specific antibodies." [Emphasis in original.] For reasons stated below, Applicant respectfully requests reconsideration.

As noted above in connection with the rejection under 35 U.S.C. 102(b), each of independent claims 1 and 17 is currently amended, in part, to specify the claimed method includes a selection step whereby an anti-PSGL-1 antibody that specifically binds to PSGL-1 on the surface of an activated T cell is selected based on ability of the anti-PSGL-1 antibody to induce apoptosis of the activated T cell. Neither Larsen nor any of Trembleau, Yago, Hirata, or Cobbold teach or suggest that any anti-PSGL-1 antibody is capable of inducing apoptosis of activated T cells. Consistent with this lack of teaching or suggestion, neither Larsen nor any of Trembleau, Yago, Hirata, or Cobbold, whether taken alone or in any combination, teach or suggest the claimed selection step. Furthermore, without any such teaching concerning apoptosis induction, the skilled person, aware of Larsen, Trembleau, Yago, Hirata, and/or

Cobbold at the time the invention was made, would have no motivation to select an anti-PSGL-1 antibody based on its ability to induce apoptosis of activated T cells, as claimed. Accordingly, the claimed invention is not obvious over Larsen in view of Trembleau, Yago, Hirata, and Cobbold and as further evidenced by Chen, as asserted by the Examiner.

Claim 10 is canceled by this Amendment, rendering moot its rejection under 35 U.S.C. § 103(a).

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of claims 1, 3, 4, 6, 10-13, 17, 19, 20, 22-25, and 38 under 35 U.S.C. § 103(a) as obvious over Larsen in view of Trembleau, Yago, Hirata, and Cobbold and as further evidenced by Chen.

In item number 14 beginning on page 19 of the Office Action, the Examiner newly rejected claims 1, 3, 4, 6, 10-13, 17, 19, 20, 22-25, and 38 under 35 U.S.C. § 103(a) as obvious over Larsen (*supra*) in view of Trembleau (*supra*), Yago (*supra*), Hirata (*supra*), and Cobbold (*supra*) and as further evidenced by Chen (*supra*) and further in view of Snapp et al. (*Blood* 104:3233-3242 (1998); "Snapp") and/or Lazarovits (*supra*) and as further evidenced by the Lin 132 Declaration filed 02/01/2007. More particularly, the Examiner asserted that Snapp and Lazarovits provide alternative anti-PSGL-1 antibodies (namely KPL1, Y1, and Y2) to substitute in the methods taught by Larsen. For reasons stated below, Applicant respectfully requests reconsideration.

The shortcomings of Larsen, Trembleau, Yago, Hirata, Cobbold, and Lazarovits in respect of the claimed method with the selection step are discussed above. Snapp similarly fails to teach or suggest that any anti-PSGL-1 antibody is capable of inducing apoptosis of activated T cells. Consistent with this lack of teaching or suggestion, Snapp likewise fails to teach or suggest the claimed selection step. Neither Larsen nor any of Trembleau, Yago, Hirata, Cobbold, Snapp, or Lazarovits, whether taken alone or in any combination, teach or suggest the claimed selection step. Furthermore, without any such teaching concerning apoptosis induction, the skilled person, aware of Larsen, Trembleau, Yago, Hirata, Cobbold, Snapp,

and/or Lazarovits at the time the invention was made, would have no motivation to select an anti-PSGL-1 antibody based on its ability to induce apoptosis of activated T cells, as claimed. Accordingly, the claimed invention is not obvious over Larsen in view of Trembleau, Yago, Hirata, and Cobbold and as further evidenced by Chen and further in view of Snapp and/or Lazarovits and as further evidenced by the Lin 132 Declaration filed 02/01/2007, as asserted by the Examiner.

Claim 10 is canceled by this Amendment, rendering moot its rejection under 35 U.S.C. § 103(a).

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of claims 1, 3, 4, 6, 10-13, 17, 19, 20, 22-25, and 38 under 35 U.S.C. § 103(a) as obvious over Larsen in view of Trembleau, Yago, Hirata, and Cobbold and as further evidenced by Chen and further in view of Snapp and/or Lazarovits and as further evidenced by the Lin 132 Declaration filed 02/01/2007.

Provisional Obviousness-Type Double Patenting Rejection

In item number 15 beginning on page 20 of the Office Action the Examiner reiterated the provisional obviousness-type double patenting rejection of instant claims 1, 3, 4, 6, 10-13, 17, 19, 20, 22-25, and 38 over claims 1, 4, 8, 9, 12-15, 19-22, 23, 26, 30, 31, and 34-38 of copending application USSN 10/662,906. Claim 10 of the instant application is canceled by this Amendment, rendering moot its provisional obviousness-type double patenting rejection. Applicant acknowledges this provisional rejection and requests it be held in abeyance until such time as the instant or copending application issues into a patent.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the application in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Dated: October 18, 2007

Respectfully submitted,

By _____

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